STATE OF MICHIGAN

DEPARTMENT OF LABOR AND ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner **File No. 90609-001**
v

Health Alliance Plan of Michigan
Respondent
_____/

Issued and entered
This 9th day of September 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On June 25, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of the Office of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. On July 1, 2008, after a preliminary review of the material submitted, the Commissioner accepted the request.

This case required review by a medical professional. Therefore, the Commissioner assigned the matter to an independent review organization (IRO). On July 16, 2008, the IRO completed its review and sent its recommendation to the Commissioner.

II
FACTUAL BACKGROUND

The Petitioner is a member of Health Alliance Plan of Michigan (HAP). Her health care benefits are defined in the HAP subscriber contract (the contract).

The Petitioner requested authorization and coverage for a continuous blood glucose monitor. HAP denied the request and the Petitioner appealed. After the Petitioner exhausted

HAP's internal grievance process, HAP maintained its denial and issued a final adverse determination letter dated May 6, 2008.

III
ISSUE

Did HAP properly deny the Petitioner authorization and coverage for a continuous blood sugar monitor?

IV
ANALYSIS

PETITIONER'S ARGUMENT

The Petitioner has a 19-year history as a type 1 diabetic. She says that in recent years she has lost the ability to sense her impending hypoglycemic (low blood sugar) episodes. The Petitioner says that because of her low blood sugar levels her family has had to call EMS several times for treatment.

The Petitioner says she tries hard to keep her blood sugar under control to prevent further damage to her vision and kidneys. Sometimes she keeps her blood sugar high to prevent the hypoglycemic episodes but that only serves to elevate her HbA1c. She also has complications associated with diabetes: renal failure, high blood pressure, and high cholesterol. The Petitioner is also trying to conceive and therefore it will be even more important to keep her sugar levels under control.

The Petitioner says she is testing her glucose levels ten or more times daily because of her hypoglycemia unawareness. She also uses an insulin pump to manage her condition, but still experiences hypoglycemic episodes.

The Petitioner had a trial using a DexCom™ continuous blood glucose monitor and it helped keep her blood sugar under control. She says the device has been determined by the Food and Drug Administration to be both safe and effective.

The Petitioner's physician, XXXXX, MD, wrote in support of the Petitioner:

> I am writing this letter on behalf of my patient [the Petitioner], who has been under my care for over two years. She does need continuous glucose monitoring coverage. This is necessary for the following medical reasons: frequent hypoglycemia with unawareness and diabetic complications including kidney problems and retinopathy.

The Petitioner wants HAP to cover a continuous glucose monitor because it is medically necessary for managing her condition.

HAP'S ARGUMENT

In an adverse determination letter dated April 13, 2007, HAP denied the Petitioner's request, saying "a continuous glucose monitor and supplies are excluded from coverage under your HAP policy."

COMMISSIONER'S REVIEW

HAP is a health maintenance organization (HMO). Section 3406p of the Insurance Code of 1956, MCL 500.3406p, requires HMOs to provide certain supplies and equipment for diabetics, including blood glucose monitors, if medically necessary. Section 3406p(3)(a) says in part:

> (3) An expense-incurred hospital, medical, or surgical policy or certificate delivered or issued for delivery in this state and a health maintenance organization contract shall include coverage for the following equipment, supplies, and educational training for the treatment of diabetes, if determined to be medically necessary and prescribed by an allopathic or osteopathic physician:
> (a) Blood glucose monitors and blood glucose monitors for the legally blind. [Emphasis added]

Section 3406p does not distinguish between standard home glucose monitoring devices and the kind of minimally invasive continuous glucose monitor sought by the Petitioner, and nothing in the section would permit an HMO to have a blanket exclusion for continuous glucose monitor devices, when they are medically necessary. HAP's medical policy (last revised in

January 2006) recognizes that continuous glucose monitoring devices have utility in certain situations and establishes the criteria that HAP uses to determine coverage:

1. Continuous glucose monitoring will be covered for Senior Plus, Medicare Complimentary and Alliance Medicare PPO members whose medical record show documentation of all of the following:
    a. Completion of a comprehensive diabetic education program
    b. Frequency of glucose self testing an average of 4 times per day
    c. Glycohemoglobin (HbA1C) values < 8
    d. Documentation of one of the following medical conditions must also be present:
        i. Frequent, unexplained hypoglycemic episodes
        ii. Unexplained, large fluctuations in their daily preprandial blood sugars and who are not well controlled as evidenced by a high HbA1C
        iii. Episodes of ketoacidosis or hospitalization for glucose out of control
        iv. Prior to starting insulin for the first time, or starting an insulin pump regime
        v. Diabetic and newly pregnant, or about to conceive
        vi. Pregnancy in a diabetic who is having trouble controlling her diabetes.
2. Must be ordered and supplied by a HAP/PHP/AHL Affiliated or Contracted Endocrinologist.

Under the "coverage" section of the Medical Policy, HAP limits the availability of this benefit to its Medicare- related products. Monitors are not available to enrollees of its traditional products, such as the product under which the Petition is enrolled. Such a limitation is not permitted under Section 3406p.

The question in this case, then, is whether a continuous blood sugar monitor is medically necessary for the Petitioner. To answer the medical question, the Commissioner assigned the matter to an IRO. The IRO expert is a practicing physician who is certified by the American Board of Internal Medicine with a subspecialty certification in endocrinology, diabetes, and metabolism. The IRO expert concluded that a continuous blood sugar monitor is medically necessary for the treatment of the Petitioner's condition.

The IRO expert noted the Petitioner's reports of wide fluctuations in blood glucose values, hypoglycemic unawareness, nephropathy, retinopathy, high blood pressure, and frequent blood glucose tests. The IRO report then said in part:

> The FDA News states "While a standard fingerstick test records a person's glucose level as a snapshot in time, the [continuous glucose monitoring system] measures glucose levels every five minutes throughout a seven-day period. This additional information can be used to detect trends and track patterns in glucose levels throughout the week that wouldn't be captured by fingerstick measurements alone."
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> Tanenberg R, et al. concluded that "use of the CGMS [continuous glucose monitoring system] to guide therapy adjustments in patients with insulin-related diabetes reduces the duration of hypoglycemia compared with therapy adjustments guided by SMBG (self-monitoring of blood glucose) values alone."
>
> The American Association of Clinical Endocrinologists (AACE) clinical practice guidelines state, "Advances in blood glucose monitoring and continuous monitoring of interstitial glucose, along with the introduction of 'smart' insulin pumps, provide clinicians and patients with powerful tools to monitor and adjust treatment regimens." "4.3.2 Clinical Considerations, Type 1 Diabetes Mellitus (T1DM) – Arrange for continuous glucose monitoring for patients with T1DM with unstable glucose control and for patients unable to achieve an acceptable HgA1C level continuous glucose monitoring is particularly valuable in detecting both unrecognized nocturnal hypoglycemia and postprandial hyperglycemia."

The IRO expert's recommendation, based on extensive expertise and professional judgment, is afforded deference by the Commissioner. The Commissioner can discern no reason why the IRO expert's judgment should be rejected in the present case. Therefore, the Commissioner accepts the IRO expert's conclusion that a continuous blood sugar monitor is medically necessary for the Petitioner.[1]

[1] The IRO expert recommended a specific brand of continuous glucose monitoring device but the Commissioner declines to accept that recommendation. The Commissioner finds that a continuous glucose monitoring device is medically necessary for the Petitioner but the decision about which device should be selected is left to the Petitioner, her physicians, and HAP.

V
ORDER

The Commissioner reverses HAP's May 6, 2008, final adverse determination. HAP shall authorize and cover a continuous blood sugar monitor and related supplies for the Petitioner.

HAP shall provide coverage for a continuous blood sugar monitor and related supplies within 60 days and shall, within seven days of providing coverage, present the Commissioner with proof it has implemented the Commissioner's Order.

To enforce this Order, the Petitioner must report any complaint regarding the implementation of this Order to the Office of Financial and Insurance Regulation, Health Plans Division, toll free 877-999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.